K062331

510(k) Summary

JUL 10 2007

General Information

Classification	Class II
Trade Name	HighPak® -12 Smart Battery
Submitter	AD Elektronik GmbH Sudentenstrasse 7-9 35883 Wetzlar Germany Tel: (49) 06641-9258-0
Contact	Daniel Kraushaar Operations Manager

Intended Use

The HighPak-12 rechargeable lithium battery is intended for use in the LifePak-12 defibrillator.

Predicate Devices

K041459	LifePak-12 Defibrillator	Medtronic	Inc./Physio-Control
K040775	LifePak-12 Defibrillator	Medtronic	Inc./Physio-Control
K010918	LifePak-12 Defibrillator	Medtronic	Inc./Physio-Control
K002445	LifePak-12 Defibrillator	Medtronic	Inc./Physio-Control
K991910	LifePak-12 Defibrillator	Medtronic	Inc./Physio-

K062331

Device Description

The HighPak -2 is a lithium manganese rechargeable battery. The outer case is molded plastic and is identical in shape and size to the predicate LifePak-12 NiCd battery. The lithium manganese cell technology offers the same voltage but an increased in amp hours resulting in longer life. It is charged in the same manner as the predicate battery and is "Smart Battery" system compatible.

Materials

All materials used in the manufacture of the HighPak -12 Battery are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included electromagnetic compatibility (EMC), charging, discharging, proper fit and operation in the LifePak-12 Defibrillator.

Summary of Substantial Equivalence

The HighPak-12 Battery is equivalent to the predicate LifePak-12 battery. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2007

AD Elektronik GmbH
c/o Mr. Gregory J. Mathison
President
Regulatory Strategies, Inc.
3924 Cascade Beach Road
Lutsen, MN 55612

Re: K062331
Trade/Device Name: HighPak-12 Rechargeable Battery
Regulation Number: 21 CFR 870.5300
Regulation Name: Auxiliary Power Supply (ac or dc) for Low-Energy dc-Defibrillator
Regulatory Class: Class II (two)
Product Code: MPD
Dated: July 6, 2007
Received: July 9, 2007

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062331

Indications for Use

510(k) Number (if known):	~~This application~~ K062331
Device Name:	HighPak® -12 Rechargeable Battery
Indications for Use:	The HighPak® -12 rechargeable lithium battery is intended for use in the LifePak-12 defibrillator.

X		
Prescription Use _ (Per 21 CFR 801.109)	OR	Over-The-Counter Use (Optional Format 1-2-9)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062331